HOUSE BILL 1222

By Hicks

AN ACT to amend Tennessee Code Annotated, Title 63, Chapter 10, relative to kidney dialysis of patients with end stage renal disease.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

- SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, Part 2, is amended by adding the following as a new section:
 - (a) This chapter does not apply to a facility to the extent the facility engages in the distribution of dialysate drugs or devices necessary to perform home peritoneal kidney dialysis to patients with end stage renal disease if:
 - (1) The dialysate drugs are comprised of dextrose or icodextrin, and the dialysate drugs and devices are approved or cleared by the federal Food and Drug Administration, as required by federal law;
 - (2) The dialysate drugs and devices are lawfully held by a manufacturer or manufacturer's agent that is properly registered with the board as a manufacturer or third-party logistics provider;
 - (3) The dialysate drugs and devices are held and delivered in their original, sealed packaging from the facility;
 - (4) The dialysate drugs and devices are delivered only by the manufacturer or the manufacturer's agent and only upon receipt of a physician's order; and
 - (5) The manufacturer or manufacturer's agent delivers the dialysate drugs and devices directly to:

- (A) Patients with end stage renal disease or such patient's designee for the patient's self-administration of the dialysis therapy; or
- (B) Healthcare providers or institutions for administration or delivery of the dialysis therapy to a patient with end stage renal disease.
- (b) The board of pharmacy retains oversight of all other drugs for peritoneal dialysis except dialysate drugs; however, the board may exempt additional drugs for peritoneal dialysis from its oversight by rules.

SECTION 2. This act shall take effect July 1, 2017, the public welfare requiring it.